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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,005	11/02/2001	Federico Mailland	9056-5CT	3851

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,005	MAILLAND, FEDERICO	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgement of Papers Received: Amendment and Declaration received 09/17/03. Claims 1-19 have been canceled and claims 41-51 have been added.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 20 – 23, 25 – 28, 30 – 38, 40 – 49 are all rejected under 35 U.S.C. 102(b) as being anticipated by Züger (USPN 5,69,911 hereafter referred to as '911). The claims were drawn to a method for improving the bioavailability of an ergot derivative comprising mixing said derivative with a pharmaceutically acceptable carrier. The ergot derivative is selected from the group consisting of α-dihydroergocryptine and bromocriptine. The excipient was selected from the group consisting of cellulose derivatives well known in the art. The claims are also drawn to a sustained-release composition comprising the ergot derivative and other common excipients well known in the art. The claims further recite that the bioavailability of the compound in increased by 25%.

'911 teaches a sustained release combination of ergot derivatives such as α-dihydroergocryptine (col. 1, lin. 55 – 60) with hydrophilic swelling agents and pharmaceutical excipients such as hydroxypropylcellulose and beeswax (col. 2, lin. 30 – 55). The reference

teaches a ratio of ergot derivative to hydrophilic swelling agent of 1:0.5 to 1:40 (col. 4, lin. 37 – col. 5, lin. 25). The reference also teaches that α-dihydroergocryptine is present in the formulation in a concentration of 1-15 mg (col. 5, lin. 14 – 24). These disclosures render the claims anticipated.

2. Claims 20, 24 – 27, 29, 41 and 47 rejected under 35 U.S.C. 102(b) as being anticipated by Fluckiger et al (USPN 3,752,888 hereafter referred to as '888). The claims were drawn to a method for improving the bioavailability of an ergot derivative comprising mixing said derivative with a pharmaceutically acceptable carrier. The ergot derivative is bromocriptine. The excipient was selected from the group consisting of cellulose derivatives well known in the art.

'888 discloses a formulation comprising an ergot derivative and swelling agents. The ergot derivative is bromocriptine (abstract). The swelling polymers include sodium carboxy methylcellulose (example and 6). The bromocriptine and the swelling agents are present in a ratio of 1:1.25 (example 5 and 6). The formulation further comprises lubricants and other excipients such as lactose and magnesium stearate (examples 1-6). The disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 39 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Fluckiger et al (USPN 3,752,888 hereafter referred to as '888). The claims are drawn to a sustained release formulation of bromocriptine having a ratio of swelling polymers to ergot derivative.

6. As discussed above '888 discloses a bromocriptine formulation comprising swelling agents. The reference discloses the ratios recited in the instant claims. The reference differs however since it is silent to the release of the ergot derivative.

7. However since the ratio of swelling agents to active ingredient is within the parameters of applicant, and no further distinctions are made to distinguish the release of the active other than the swelling polymer, it is the position of the examiner that the products of '888 would have similar if not identical release of the instant invention. It would be obvious to a skilled artisan to use the formulation of '888 to deliver a sustained release formulation identical to that of applicant since the only criteria to differentiate a sustained release formulation from a non-sustained release formulation is swelling agent ratio. Also since the ratio falls within the range of applicant, it would be obvious for a skilled artisan to assume that the bioavailability of the formulation was improved according to the formulation. Again the criteria given by applicant

are for a particular ratio, which is disclosed in the prior art. It would be inherent to the formulation to have an improved bioavailability according to the criteria established by the instant claims.

One of ordinary skill in the art would be motivated to administer the composition of '888 as a sustained release delivery in order to improve the delivery and administration of the ergot derivative. It would have been within the level of skill in the art to delivery the composition of '888 as a sustained release formulation with improved bioavailability since the composition discloses an ideal ratio such pharmacology. It would have been obvious for a skilled artisan to follow the suggestions with an expected result of a sustained release formulation of bromocriptine with improved bioavailability.

Response to Amendment

8. The Declaration under 37 CFR 1.132 filed 09/17/03 is insufficient to overcome the rejection of claims 20 – 40 based upon USC 102 (b) and 103 (a) as set forth in the last Office action because: The declaration is not commensurate with the scope of the instant claims. The declaration is drawn to a specific example of an ergot derivative formulation, while the claims are drawn to a generic formulation. The examples of the declaration disclose specific concentrations, which are not represented in the instant claims. Also the declaration cannot be used to overcome 102(b) rejection since the rejection is based on one of the anticipation and not of obviousness.

Response to Arguments

9. Applicant's arguments filed 9/17/03 have been fully considered but they are not persuasive.

Claims Rejection Under 35 USC 102:

Applicant argues that '888 does not in fact teach a composition comprising ergot derivatives and swelling agents in a ratio from 1:0.5 to 1:2. The examiner agrees with this assessment, yet draw applicant's attention to col. 4, lin. 44 – 68 where the ratios of ergot derivatives including dihydroergocryptine range from 1:4 to 1:25, which falls within the 1:0.5 to about 1:5 range of the instant claims. Also the examiner directs applicant's attention to col. 5, lin. 14 – 25, which discloses that dihydroergocryptine is present in the formulation in 1-15 mg dosages. In view of these disclosures, the claims remain rejected.

Election/Restrictions

10. This application contains claims directed to the following patentably distinct species of the claimed invention: a) α-dihydroergocryptine and b) bromocriptine

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 20 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7648.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600